# UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA NORTHEASTERN DIVISION

EDWIN R. BANKS,	)	
	)	
Plaintiff,	)	
	)	
V.	)	Case 5:20-cv-0565-LCB
	)	
ALEX M. AZAR, in his official	)	
capacity as Secretary of the U.S.,	)	
Department of Health and Human	)	
Services,	)	
	)	
Defendant.	)	

# **ANSWER**

Defendant, Alex M. Azar, in his official capacity as Secretary of the United States Department of Health and Human Services ("Secretary"), by and through the United States Attorney, hereby answers the Complaint:

## FIRST DEFENSE

The final agency decision of the Secretary ("Final Agency Decision"), rendered by an Administrative Law Judge in the Office of Medicare Hearings and Appeals in the United States Department of Health and Human Services, is found in the certified Administrative Record ("AR") at 1251-1262. The Final Agency Decision is in accordance with the applicable legal standards and is supported by substantial evidence, and therefore is due to be affirmed.

#### **SECOND DEFENSE**

The Secretary reserves the right to plead any other affirmative defenses or any other applicable law.

#### THIRD DEFENSE

Plaintiff fails to state a claim for which relief can be granted under the Administrative Procedure Act, 5 U.S.C. § 701, et seq.

## FOURTH DEFENSE

The unnumbered opening paragraph of the Complaint consists of Plaintiff's characterizations and discussion of the nature of his civil action, to which no answer is necessary. To the extent an answer is deemed to be required, the allegations are denied.

The designation "Jury Trial Demanded" in the caption is denied. This is a civil action for judicial review of a final agency decision, for which a "jury trial" is unavailable and inapplicable.

Answering the allegations in the numbered paragraphs of the Complaint, and using the same paragraph numbering, the Secretary answers as follows:

1. This paragraph consists of Plaintiff's characterization of this action, to which no answer is required. To the extent an answer is deemed to be required, the Secretary denies the allegations.

- 2. This paragraph consists of Plaintiff's characterization of this action, to which no answer is required. To the extent an answer is deemed to be required, the Secretary denies the allegations.
- 3. This paragraph consists of Plaintiff's characterization of this action and of general positions allegedly taken by the Secretary, to which no answer is required. To the extent an answer is deemed to be required, the Secretary denies the allegations.
- 4. The Secretary admits only that Plaintiff Edwin R. Banks ("Banks") has been diagnosed with a form of brain cancer, glioblastoma multiforme (GBM). The Secretary denies the remaining allegations in this paragraph. The statement in the footnote is an extra-record statement and is not material to the Court's review.
- 5. The Secretary admits only that Plaintiff Banks timely filed this suit and that this Court has jurisdiction over this civil action pursuant to 42 U.S.C. § 1395ff(b)(1)(A), which incorporates 42 U.S.C. § 405(g). The Secretary denies that the Medicare Appeal Council rendered a decision denying the claims at issue in Plaintiff Banks' case.
  - 6. The Secretary admits that venue is proper in this Court.
- 7. The allegations contained in this paragraph pertain to Plaintiff Roy Wilmoth, Jr ("Wilmoth"). Wilmoth's claims have been severed and transferred to

the United States District Court for the Northern District of Mississippi, therefore no answer is required herein.

- 8. The Secretary admits the allegations in this paragraph.
- 9. The allegations contained in this paragraph pertain to Plaintiff Maureen Piekanski ("Piekanski"). Piekanski's claims have been severed and transferred to the United States District Court for the Middle District of Pennsylvania, therefore no answer is required herein.
  - 10. The Secretary admits the allegations in this paragraph
- 11. This paragraph consists of Plaintiff's legal citation and quotation and legal conclusions, to which no answer is necessary. To the extent an answer is deemed to be required, the allegations are denied.
- 12. This paragraph consists of Plaintiff's legal citation and legal conclusions, to which no answer is necessary. To the extent an answer is deemed to be required, the allegations are denied.
- 13. The Secretary admits only that GBM is a form of brain cancer. The Secretary is without sufficient knowledge to ascertain the truth of the remaining allegations in this paragraph. To the extent an answer is deemed to be required, the Secretary denies those allegations.
- 14. The Secretary admits the allegations in sentences one and two. The Secretary is without sufficient knowledge to ascertain the truth of the remaining

allegations in this paragraph. To the extent an answer is deemed to be required, the Secretary denies those allegations. Footnote 2 consists of Plaintiff's extra-record characterizations of the nature of scientific studies, to which no answer is required. To the extent an answer is deemed to be required, the Secretary denies the allegations.

- 15. This paragraph contains Plaintiff's characterization of two medical articles contained in the AR and to which no answer is required. The Court is respectfully referred to AR 1997-2006 and 1986-1996 for the documents' true, full, and correct contents. Footnote 3 consists of Plaintiff's extra-record statement and is not material to the Court's review. Footnote 4 consists of Plaintiff's citations to the articles and to which no answer is required. The Court is referred to the articles in the AR. To the extent an answer is deemed to be required to the allegations in this paragraph or to footnotes 3 or 4, the Secretary denies the allegations.
- 16. The Secretary is without sufficient knowledge to ascertain the truth of the allegations in this paragraph. To the extent an answer is deemed to be required, the Secretary denies the allegations.
- 17. The Secretary is without sufficient knowledge to ascertain the truth of the allegations in this paragraph. To the extent an answer is deemed to be required, the Secretary denies the allegations.

- 18. This paragraph consists of Plaintiff's characterization of aspects of the Medicare appeals process, to which no answer is required. To the extent an answer is deemed to be required, the Secretary denies the allegations in this paragraph as stated.
- 19. This paragraph consists of Plaintiff's characterization of aspects of the Medicare appeals process, to which no answer is required. To the extent an answer is deemed to be required, the Secretary denies the allegations in this paragraph.
- 20. The allegations contained in this paragraph pertain to Wilmoth. Wilmoth's claims have been severed and transferred to the United States District Court for the Northern District of Mississippi, therefore no answer is required herein.
- 21. The allegations contained in this paragraph pertain to Wilmoth. Wilmoth's claims have been severed and transferred to the United States District Court for the Northern District of Mississippi, therefore no answer is required herein
- 22. The allegations contained in this paragraph pertain to Wilmoth. Wilmoth's claims have been severed and transferred to the United States District Court for the Northern District of Mississippi, therefore no answer is required herein
- 23. The allegations contained in this paragraph pertain to Wilmoth. Wilmoth's claims have been severed and transferred to the United States District Court for the Northern District of Mississippi, therefore no answer is required herein.

- 24. The allegations contained in this paragraph pertain to Wilmoth. Wilmoth's claims have been severed and transferred to the United States District Court for the Northern District of Mississippi, therefore, no answer is required herein
- 25. The allegations contained in this paragraph pertain to Wilmoth. Wilmoth's claims have been severed and transferred to the United States District Court for the Northern District of Mississippi, therefore no answer is required herein.
- 26. The allegations contained in this paragraph pertain to Wilmoth. Wilmoth's claims have been severed and transferred to the United States District Court for the Northern District of Mississippi, therefore no answer is required herein.
- 27. The allegations contained in this paragraph pertain to Wilmoth. Wilmoth's claims have been severed and transferred to the United States District Court for the Northern District of Mississippi, therefore no answer is required herein
- 28. The allegations contained in this paragraph pertain to Wilmoth. Wilmoth's claims have been severed and transferred to the United States District Court for the Northern District of Mississippi, therefore no answer is required herein
- 29. The allegations contained in this paragraph pertain to Wilmoth. Wilmoth's claims have been severed and transferred to the United States District Court for the Northern District of Mississippi, therefore no answer is required herein.

- 30. The allegations contained in this paragraph pertain to Wilmoth. Wilmoth's claims have been severed and transferred to the United States District Court for the Northern District of Mississippi, therefore no answer is required herein.
- 31. The Secretary is without sufficient knowledge to ascertain the truth of the allegations in this paragraph. To the extent an answer is deemed to be required, the Secretary denies the allegations.
- 32. The Secretary admits only that Plaintiff has been diagnosed with GBM, received specific treatments listed in the Final Agency Decision, and was then prescribed tumor treatment field therapy (TTFT). See AR 1252.
- 33. This paragraph contains Plaintiff's characterization of the ALJ decision resolving ALJ Appeal Nos. 1-8498071113, 1-8428973391 and 1-8501252025, to which no answer is required. The Court is respectfully referred to AR 1273-1279 for the document's true, full, and correct contents. To the extent an answer is deemed to be required, the Secretary denies the allegations.
- 34. The Secretary admits the allegations contained in this paragraph, but denies any suggestion that the decision has precedential value.
- 35. This paragraph contains Plaintiff's characterizations of ALJ Appeal No. 1-813649506, to which no answer is required. The Court is respectfully referred to AR 1251-1262 for the document's true, full, and correct contents.

- 36. This paragraph contains Plaintiff's characterizations of his appeal of ALJ Appeal No. 1-813649506 to the Medicare Appeals Council, to which no answer is required. The Court is respectfully referred to AR 1304-1310 for the document's true, full, and correct contents.
- 37. This paragraph contains Plaintiff's characterizations of Plaintiff's notice of escalation and of certain statutory and regulatory provisions, to which no answer is required. The Court is respectfully referred to AR 1267 for Plaintiff's request for escalation and the language in the cited statutory and regulatory provisions. The Secretary admits only that Plaintiff is entitled to judicial review of ALJ Appeal No. ALJ Appeal No. 1-813649506 as circumscribed by 42 U.S.C. § 1395ff(b)(1)(A), which incorporates 42 U.S.C. § 405(g).
- 38. The allegations contained in this paragraph pertain to Piekanski. Piekanski's claims have been severed and transferred to the United States District Court for the Middle District of Pennsylvania, therefore no answer is required herein.
- 39. The allegations contained in this paragraph pertain to Piekanski. Piekanski's claims have been severed and transferred to the United States District Court for the Middle District of Pennsylvania, therefore no answer is required herein.
- 40. The allegations contained in this paragraph pertain to Piekanski. Piekanski's claims have been severed and transferred to the United States District Court for the Middle District of Pennsylvania, therefore no answer is required herein.

- 41. The allegations contained in this paragraph pertain to Piekanski. Piekanski's claims have been severed and transferred to the United States District Court for the Middle District of Pennsylvania, therefore no answer is required herein.
- 42. The allegations contained in this paragraph pertain to Piekanski. Piekanski's claims have been severed and transferred to the United States District Court for the Middle District of Pennsylvania, therefore no answer is required herein.
- 43. The allegations contained in this paragraph pertain to Piekanski. Piekanski's claims have been severed and transferred to the United States District Court for the Middle District of Pennsylvania, therefore no answer is required herein.
- 44. The allegations contained in this paragraph pertain to Piekanski. Piekanski's claims have been severed and transferred to the United States District Court for the Middle District of Pennsylvania, therefore no answer is required herein.
- 45. The allegations contained in this paragraph pertain to Piekanski. Piekanski's claims have been severed and transferred to the United States District Court for the Middle District of Pennsylvania, therefore no answer is required herein.
- 46. The allegations contained in this paragraph pertain to Piekanski. Piekanski's claims have been severed and transferred to the United States District Court for the Middle District of Pennsylvania, therefore no answer is required herein.

- 47. The allegations contained in this paragraph pertain to Piekanski. Piekanski's claims have been severed and transferred to the United States District Court for the Middle District of Pennsylvania, therefore no answer is required herein.
- 48. The allegations contained in this paragraph pertain to Piekanski. Piekanski's claims have been severed and transferred to the United States District Court for the Middle District of Pennsylvania, therefore no answer is required herein.
- 49. This paragraph consists of Plaintiff's incorporation of his allegations in paragraphs 1 through 48 of the Complaint. Accordingly, the Secretary incorporates his answers to paragraphs 1 through 48 as if fully set forth herein.
- 50. This paragraph consists of Plaintiff's request for relief to which no answer is necessary. To the extent an answer is deemed to be required, the Secretary denies that Plaintiff is due any relief.
- 51. This paragraph consists of Plaintiff's request for relief, to which no answer is necessary. To the extent an answer is deemed to be required, the Secretary denies that Plaintiff is due any relief. The Secretary denies that the Administrative Procedure Act, 5 U.S.C. § 706, governs the Court's review. The standard of review for this action is that set out at 42 U.S.C. § 405(g), incorporated by 42 U.S.C. § 1395ff(b)(1).

- 52. This paragraph consists of Plaintiff's incorporation of his allegations in paragraphs 1 through 51 of the Complaint. Accordingly, the Secretary incorporates his answers to paragraphs 1 through 51 as if fully set forth herein.
- 53. This paragraph consists of Plaintiff's request for relief to which no answer is necessary. To the extent an answer is deemed to be required, the Secretary denies that Plaintiff is due any relief. The Secretary denies that the Administrative Procedure Act, 5 U.S.C. § 706, governs the Court's review. The standard of review for this action is that set out at 42 U.S.C. § 405(g), incorporated by 42 U.S.C. § 1395ff(b)(1).
- 54. This paragraph consists of Plaintiff's incorporation of his allegations in paragraphs 1 through 53 of the Complaint. Accordingly, the Secretary incorporates his answers to paragraphs 1 through 53 as if fully set forth herein.
- 55. This paragraph consists of Plaintiff's request for relief to which no answer is necessary. To the extent an answer is deemed to be required, the Secretary denies that Plaintiff is due any relief. The Secretary denies that the Administrative Procedure Act, 5 U.S.C. § 706, governs the Court's review. The standard of review for this action is that set out at 42 U.S.C. § 405(g), incorporated by 42 U.S.C. § 1395ff(b)(1).

- 56. This paragraph consists of Plaintiff's incorporation of his allegations in paragraphs 1 through 55 of the Complaint. Accordingly, the Secretary incorporates his answers to paragraphs 1 through 55 as if fully set forth herein.
- 57. This paragraph consists of Plaintiff's request for relief, to which no answer is necessary. To the extent an answer is deemed to be required, the Secretary denies that Plaintiff is due any relief. The Secretary denies that the Administrative Procedure Act, 5 U.S.C. § 706, governs the Court's review. The standard of review for this action is that set out at 42 U.S.C. § 405(g), incorporated by 42 U.S.C. § 1395ff(b)(1).
- 58. This paragraph consists of Plaintiff's incorporation of his allegations in paragraphs 1 through 56 of the Complaint. Accordingly, the Secretary incorporates his answers to paragraphs 1 through 56 as if fully set forth herein.
- 59. This paragraph consists of Plaintiff's request for relief, to which no answer is necessary. To the extent an answer is deemed to be required, the Secretary denies that Plaintiff is due any relief. The Secretary denies that the Administrative Procedure Act, 5 U.S.C. § 706, governs the Court's review. The standard of review for this action is that set out at 42 U.S.C. § 405(g), incorporated by 42 U.S.C. § 1395ff(b)(1).

The remainder of the Complaint consists of Plaintiff's prayer for relief, to which no answer is required.

The Secretary denies that Plaintiff is due any relief.

Anything not specifically admitted above is denied.

WHEREFORE, having fully answered, the Secretary prays for judgment in his favor and asks the Court to grant such further relief as may be appropriate.

Respectfully submitted this 28th day of May.

JAY E. TOWN United States Attorney

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